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PATENT

Attorney Docket No.: S-9-6

Commissioner for Patents,
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On Feb. 22, 2006

By [Signature]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:
Lewis Sharps et al.

Application No. 10/613,115

Filing Date: July 3, 2003

Title: METHODS FOR REPAIRING
DAMAGED INTERVERTEBRAL DISCS

)
)
) Examiner: Lee Cohen

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) Art Unit: 3739

)
)
) COMMUNICATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The following information is being brought to the Examiner's attention.

I. LITIGATION ACTIVITY

Smith & Nephew litigation

On July 25, 2001, ArthroCare Corporation commenced an action in the United States District Court for the District of Delaware against Smith & Nephew, Inc. ("Smith & Nephew") for infringement of U.S. Patent Nos. 5,697,536 ("the '536 Patent"), 5,697,882 ("the '882 Patent") and 6,224,592 ("the '592 Patent"). That action was assigned Civil Action No. 01-504-SLR (the "*Smith & Nephew* litigation"). The *Smith & Nephew* litigation proceeded to trial commencing on April 30, 2003. On May 12, 2003, the jury returned a verdict in favor of ArthroCare on infringement and validity issues with respect to all three patents. Thereafter, on June 20, 2003, the Court entered judgment on the jury's verdict.

In addition, a number of post trial motions were filed on the issues of infringement, invalidity, and inequitable conduct. In particular, Smith & Nephew filed a motion for judgment as a



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TRANSMITTAL FORM

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Total Number of Pages in This Submission

Application Number	10/613,115
Filing Date	July 3, 2003
First Named Inventor	Lewis Sharps, et al.
Art Unit	3739
Examiner Name	Lee Cohen
Attorney Docket Number	S-9-6

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): COMMUNICATION
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Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	ArthroCare Corporation		
Signature			
Printed name	Richard R. Batt		
Date	02/22/06	Reg. No.	43,485

CERTIFICATE OF TRANSMISSION/MAILING

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Signature			
Typed or printed name	Michelle Nicely	Date	02/22/06

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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matter of law; a motion for a new trial; a cross motion to strike ArthroCare's motion for entry of judgment of no inequitable conduct and a motion to modify the protective order. ArthroCare filed a motion for entry of judgment of no inequitable conduct and a motion for a permanent injunction.

On March 10, 2004 the Court ruled in favor of ArthroCare on all post trial motions. The Court issued a 90 page memorandum opinion: 1.) denying Smith & Nephew's motion for judgment as a matter of law; 2.) denying Smith & Nephew's motion for a new trial; 3.) granting ArthroCare's motion for entry of judgment of no inequitable conduct; 4.) denying Smith & Nephew's cross motion to strike ArthroCare's motion for entry of judgment of no inequitable conduct; 5.) granting ArthroCare's motion for a permanent injunction; and 6.) denying Smith & Nephew's motion to modify the protective order.

The Court also issued, on March 10, 2004, a memorandum opinion granting ArthroCare's motion to dismiss Smith & Nephew's antitrust counterclaims.

The above mentioned memorandum opinions and corresponding orders are enclosed for your consideration.³

On June 9, 2004, the Court issued an order enjoining Smith and Nephew from directly infringing, inducing the infringement, and contributing to the infringement of the '536 Patent, the '882 Patent and the '592 Patent. The above mentioned memorandum opinions and corresponding orders are enclosed for your consideration⁴. Smith & Nephew has appealed the judgment and the injunction to the United States Court of Appeals for the Federal Circuit.

On May 10, 2005, the Federal Circuit Court of Appeals issued a decision (attached) in connection with the lawsuit between ArthroCare and Smith & Nephew. In its decision, the Court, among other things, upheld the jury's verdict in favor of ArthroCare on U.S. Patent Nos. 5,697,882 and 6,224,592, but reversed the jury's verdict as to the validity of claims 46, 47, and 56 of U.S. Patent No. 5,697,536.

On May 23, 2005, Patentee filed a Combined Petition for Panel Rehearing and Rehearing *En Banc* (attached). The Petition specifies several points of law and fact overlooked or misapprehended by the Court of Appeals for the Federal Circuit in its May 10, 2005 Decision relating to the '536 Patent,

³ A portion of the memorandum opinion discussing the antitrust issues has been redacted to preserve information that is confidential.

⁴ A portion of the memorandum opinion discussing the antitrust issues has been redacted to preserve information that is confidential.

the '882 Patent, and the '592 Patent. The Court issued an Order, dated July 12, 2005, denying Patentee's request for a panel rehearing and rehearing *En Banc*.

On September 2, 2005, ArthroCare and Smith & Nephew entered into a settlement agreement settling the legal disputes arising from the *Smith & Nephew* litigation. Attached is the Form 8-k, dated September 9, 2005, filed in connection with this material definitive agreement between ArthroCare and Smith & Nephew.

In addition to the above-listed materials, there are numerous other papers that were filed with the Court or served in connection with the *Smith & Nephew* litigation that relate to invalidity or enforceability issues. These include, for example, the expert reports of Dr. S. Nahum Goldberg (ArthroCare's expert on infringement and validity), Dr. Kenneth Taylor (Smith & Nephew's expert on infringement and invalidity), Dr. Kim Manwaring (Smith & Nephew's expert on invalidity), Dr. Michael Choti (Smith & Nephew's expert on infringement and invalidity), Charles Van Horn (ArthroCare's expert on patent prosecution issues), and Ronald Panitch (Smith & Nephew's expert on patent prosecution issues). Smith & Nephew also served a paper purportedly prepared by Dr. Brian Skromme of Arizona State University related to the validity of the '882 patent. Moreover, the parties filed motions for summary judgment on issues pertaining to the validity of the patents-in-suit. The briefs in support of and opposition to these motions are listed as docket numbers 247, 248, 257, 258, 261, 262, 280, 283, 292, 298, 300, and 302 on the official docket that ArthroCare has enclosed. Smith & Nephew also produced a declaration from Eberhard Roos, the named inventor on U.S. Patent No. 4,116,198 and co-author of the Roos and Elsasser article ("Über ein Instrument zur leckstromfreien transurethralen Resektion"), both of which were references asserted in the *Smith & Nephew* litigation. There also are many trial exhibits. In addition, pre-trial depositions were taken of several witnesses regarding validity and enforceability issues, including depositions of Dr. Goldberg, Dr. Taylor, Dr. Manwaring, Dr. Choti, Mr. Van Horn, and Mr. Panitch. A list of the depositions taken in the *Smith & Nephew* litigation is set forth below:

1. John Tighe, taken September 18, 2002 and November 8, 2002 (ArthroCare employee, fact witness);
2. Diane DeLucia, taken September 19, 2002 (Smith & Nephew employee, fact witness);
3. John Raffle, taken September 19, 2002 and November 11, 2002 (ArthroCare employee and patent attorney, fact witness);
4. James Heslin, taken September 24, 2002 (patent attorney, fact witness);
5. Fernando Sanchez, taken September 24, 2002 (ArthroCare employee, fact witness);
6. Duane Marion, taken September 28, 2002 (former Smith & Nephew employee, fact witness);

7. John Graf, taken October 1, 2002 (Smith & Nephew employee, fact witness);
8. Hira Tahpliyal, taken October 1, 2003 and November 14, 2002 (co-inventor of patents-in-suit, fact witness);
9. Jim Pacek, taken October 3, 2002 and November 7, 2002 (ArthroCare employee, fact witness);
10. John Konsin, taken October 3, 2002 (Smith & Nephew employee, fact witness);
11. Jean Woloszko, taken October 3, 2002 (ArthroCare employee, fact witness);
12. Andrew Eggers, taken October 4, 2002 (employee of Eggers & Associates (owned by Philip E. Eggers, co-inventor of patents-in-suit), fact witness);
13. Bruce Prothro, taken October 4, 2002 (ArthroCare employee, fact witness);
14. Kara Weldon, taken October 5, 2002 (current or former Smith & Nephew employee, fact witness);
15. David Balford, taken October 5, 2002 (Smith & Nephew employee, fact witness);
16. Allen Weinstein, taken October 8, 2002 (ArthroCare employee, fact witness);
17. Christine Hanni, taken October 10, 2002 (former ArthroCare employee, fact witness);
18. Linda Guthrie, taken October 11, 2002 (Smith & Nephew employee, fact witness);
19. Michael Baker, taken October 11, 2002 (ArthroCare CEO, fact witness);
20. Kate Knudsen, taken October 11, 2002 and November 7, 2002 (Smith & Nephew employee, fact witness);
21. Sally Maher, taken October 11, 2002 (Smith & Nephew employee, fact witness);
22. Ron Sparks, taken October 11, 2002 (Smith & Nephew CEO, fact witness);
23. Philip E. Eggers, taken October 15 and 29, 2002, November 13, 2002, and April 30, 2003 (co-inventor of patents-in-suit, fact witness);
24. Tom Ross, taken October 15, 2002 (current or former employee of Oratec Interventions, Inc. (acquired by Smith & Nephew), fact witness);
25. Jack Cordes, taken October 15, 2002 (former employee of Eggers & Associates, fact witness);
26. Michael Long, taken October 29, 2002 (former Smith & Nephew employee, fact witness);
27. Joan McCreary, taken October 30, 2002 (Smith & Nephew employee, fact witness);
28. Todd Plevinsky, taken October 31, 2002 (former Smith & Nephew employee, fact witness);
29. Karen Drucker, taken November 1 and 14, 2002 (Smith & Nephew employee, fact witness);
30. Allen Gannon, taken November 1, 2002 (Smith & Nephew employee, fact witness);
31. Jim Pacek, taken November 7, 2002 (ArthroCare employee, fact witness);
32. Tim Crabtree, taken November 7, 2002 (former Smith & Nephew employee, fact witness);

33. John Konsin, taken November 7, 2002 (Smith & Nephew employee, fact witness);
34. Jason Krieser, taken November 13, 2003 (Smith & Nephew employee, fact witness);
35. Dr. Kim Manwaring, taken March 20, 2003 (Smith & Nephew expert witness);
36. Dr. Eliot Leitman, taken March 25, 2003 (ArthroCare expert witness);
37. Dr. Kenneth Taylor, taken March 27 and 28, 2003 (Smith & Nephew expert witness);
38. Dr. S. Nahum Goldberg, taken March 27 and 28, 2003 (ArthroCare expert witness);
39. Ronald Panitch, taken March 28, 2003 (Smith & Nephew expert witness);
40. Dr. Michael Choti, taken March 30, 2003 (Smith & Nephew expert witness);
41. Charles Van Horn, taken April 3, 2003 (ArthroCare expert witness);
42. Creighton Hoffman, taken April 4, 2003 (ArthroCare expert witness);
43. Brian Napper, taken April 17, 2003 (Smith & Nephew expert witness);
44. Warren Heim, taken April 22, 2003 (consultant to Smith & Nephew, fact witness).

Smith & Nephew designated many of the materials from the *Smith & Nephew* litigation as confidential pursuant to the protective order in that case. Without admitting the materiality or relevance of the foregoing materials, Applicant will submit any or all of the foregoing materials to the Examiner for consideration or, if the Examiner requests materials that have been filed under seal or designated confidential pursuant to the protective order, Applicant will contact Smith & Nephew in an attempt to secure an agreement by which such materials can be disclosed.

II. REEXAMINATION

A. The '536 Patent

On December 23, 1999, an *Ex Parte* Reexamination Request ("Request") for the '536 Patent was filed with the PTO. Applicant has enclosed a copy of the file history for the '536 Reexamination with this Information Disclosure Statement. The Request sought reexamination of claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60, and 63 of the '536 Patent in light of U.S. Patent 4,116,198 ("the Roos '198"). The PTO granted the Request on October 27, 2000.

On November 15, 2002, the PTO mailed an Office Action. The Office Action is divided into two sections. Section I sets forth the conclusion of the examiner and a board of primary examiners that "the Roos '198 does not anticipate or render obvious any of the independent claims of record." *See* November 15, 2002 Office Action at 3. Section II contains a rejection of claims 1-64 of the '536 Patent as anticipated under 35 U.S.C. § 102(b) and obvious under 35 U.S.C. § 103 in light of certain references

identified in an Information Disclosure Statement filed by Applicant on June 19, 2002. On December 19, 2002, Applicant submitted a Response to the Office Action.

On March 14, 2003, the PTO issued a Notice of Intent to Issue *Ex Parte* Reexamination Certificate ("NIRC"). The NIRC states that "the examiner of record concurs with the arguments presented by patent Applicant on paper number 15. Accordingly, it is concluded that claims 1-64 are allowable over the prior art of record." See NIRC at 2. A Reexamination Certificate issued on June 10, 2003.

Additionally, on April 9, 2003, another *Ex Parte* Reexamination Request for the '536 Patent was filed with the PTO. The Request sought reexamination of claims 1, 2, 5, 9, 14, 15, 25, 26, 28, 30-33, 36, 38, 40, 42-47, 49, 53, 55, 56, 58, 59, 61, and 63 of the '536 Patent in light of the Roos '198; Elasser and Roos, "Uber ein Instrument zur leckstromfreien transurethralen resection," Medizinal-Markt/Acto Medicotechnica, Vol. 24, No. 4/1976, pp. 129-134 ("the Elasser and Roos article"); U.S. Patent Nos. 4,805,616; 4,674,499; 4,381,007; 5,217,459; and 5,007,908. The PTO granted the Request on June 30, 2003. It has been assigned Reexamination No. 90/006,597.

An Office Action issued on November 18, 2004. Applicant filed a timely reply on January 18, 2005.

B. The '882 Patent

On April 18, 2003, an *Ex Parte* Reexamination Request for the '882 Patent was filed with the PTO. The Request sought reexamination of claims 1, 13, 17, 18, 24, 26, 28, 29, 48 and 54 of the '882 Patent in light of U.S. Patent Nos. 5,122,138; 5,007,908; and Slager et al., "Vaporization Of Atherosclerotic Plaques By Spark Erosion," JACC Vol. 5, No. 6, June 1985:1382-6 ("the Slager Article"). The PTO granted the Request on July 1, 2003. It has been assigned Reexamination No. 90/006,607.

An Office Action issued on February 18, 2005. Applicant filed a timely reply on April 18, 2005

C. The '592 Patent

On April 21, 2003, an *Ex Parte* Reexamination Request for the '592 Patent was filed with the PTO. The Request sought reexamination of claims 1, 3, 4, 9, 11, 21, 23, 26, 27, 30, 32 and 42 of the '592 Patent in light of the Roos '198; the Elasser and Roos article; U.S. Pat. Nos. 4,381,007 to Doss; and the Slager Article. The PTO granted the Request on July 7, 2003. It has been assigned Reexamination No. 90/006,611.

An Office Action issued on April 14, 2005 and April 26, 2005. Applicant filed a timely reply on June 27, 2005.

Should the Examiner desire copies of any of the documents filed in connection with the above reexaminations Applicant will submit them upon a request to do so in writing from the Examiner.

III. CO-PENDING PATENT APPLICATIONS

The following is a list of co-pending applications:

Application No.	Filing Date	Application No.	Filing Date
09/293,231	16-Apr-1999	10/661,118	12-Sep-2003
09/314,247	18-May-1999	10/656,597	05-Sep-2003
09/338,842	23-Jun-1999	10/682,600	09-Oct-2003
09/347,390	06-Jul-1999	10/713,643	13-Nov-2003
09/354,835	16-Jul-1999	10/735,477	11-Dec-2003
09/372,454	11-Aug-1999	10/774,222	05-Feb-2004
09/457,201	06-Dec-1999	10/799,908	12-Mar-2004
09/501,327	09-Feb-2000	10/799,491	12-Mar-2004
09/512,742	24-Feb-2000	10/903,655	29-Jul-2004
09/562,496	01-May-2000	10/970,796	20-Oct-2004
09/586,295	02-Jun-2000	11/028,790	03-Jan-2005
09/679,394	03-Oct-2000	11/089,879	25-Mar-2005
09/747,311	20-Dec-2000	11/105,274	12-Apr-2005
09/796,094	28-Feb-2001	11/114,610	25-Apr-2005
09/839,427	20-Apr-2001	11/125,613	09-Mar-2005
09/963,736	03-May-2001	11/130,931	16-May-2005
10/072,599	05-Feb-2002	11/144,934	03-Jun-2005
10/097,763	13-Mar-2002	11/166,545	24-Jun-2005
10/139,117	03-May-2002	11/176,803	06-Jul-2005
10/187,733	27-Jun-2002	11/204,811	15-Aug-2005
10/264,308	02-Oct-2002	11/230,360	19-Sep-2005
10/288,227	04-Nov-2002	11/233,556	22-Sep-2005
10/290,930	07-Nov-2002	11/246,967	07-Oct-2005
10/290,930	07-Nov-2002	11/248,460	11-Oct-2005
10/291,213	08-Nov-2002	11/249,691	12-Oct-2005
10/339,470	09-Jan-2003	11/254,383	20-Oct-2005
10/367,608	13-Feb-2003	11/270,344	09-Nov-2005
10/372,591	21-Feb-2003	11/285,927	23-Nov-2005
10/374,411	25-Feb-2003	11/327,553	06-Jan-2006
10/384,050	05-Mar-2003	11/327,089	06-Jan-2006
10/389,159	13-Mar-2003		
10/621,839	16-Jul-2003		
10/437,260	13-May-2003		
10/402,728	28-Mar-2003		
10/392,529	20-Mar-2003		
10/389,159	14-Mar-2003		
10/613,609	02-Jul-2003		
10/435,825	12-May-2003		
10/613,115	03-Jul-2003		
10/621,839	16-Jul-2003		

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'RR Batt', with a stylized flourish at the end.

Richard R. Batt
Reg. No. 43,485

ArthroCare Corporation
680 Vaqueros Avenue
Sunnyvale, California 94085-3523
(408) 736-0224